GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3347
ANSWERED ON:18.12.2015
Generic Drugs
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has drawn any action plan to promote and improve access to the generic drugs to boost healthcare services in the country;

(b) if so, the details thereof indicating the financial and operational modalities worked out for the purpose, State/UT-wise;

(c) the measures taken/proposed to be taken by the Government to impress upon the doctors including those working under the Central Government Health Scheme (CGHS) and in private healthcare facilities to prescribe generic drugs; and

(d) the other steps being taken by the Government to ensure the quality, safety and standards of the generic drugs in the country?

Answer

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) & (b): Public Health being a state subject, the primary responsibility of providing improved access to generic drugs lies with the State/UT governments. Under the National Health Mission (NHM), financial support is provided to the States/UTs for strengthening their healthcare delivery system including support for provision of free generic drugs to those who access public health facilities based on the requirement posed by the States/UTs in their Programme Implementation Plans. An incentive of upto 5% additional funding under the NHM is provided to those states that introduce free generic/essential drugs. Further, the central government has launched the Jan Aushadhi Scheme to make available generic medicines at affordable pric es to all through Jan Aushadhi Stores (JAS). The Government has developed and issued operational guidelines for Free Drugs Service Initiative to provide guidance to the States

The details of Approvals & Expenditure for Procurement of Drugs under NHM for the FY 2015-16 is at Annexure.

(c): A number of steps have been taken by the Government to promote use of generic medicines. Circulars/ instructions have been issued from time to time to all Central Government hospitals, CGHS dispensaries and State Governments for encouraging prescription of generic medicines. Besides, the Code of Medical Ethics under Indian Medical Council Regulations, 2002 also mandates prescription of drugs with generic names.

(d): The steps taken by the Government to check Spurious/Sub-Standard Drugs including generic in the country include:
I. amending the Drugs and Cosmetics Act, 1940 by the Drugs & Cosmetics (Amendment) Act, 2008 to provide for more stringent penalties for manufacture and trade of spurious and adulterated drugs.

II. making provisions in the Drugs & Cosmetics (Amendment) Act, 2008 for setting up of Special designated courts for speedy disposal of cases to deal with the cases of offences under the Drugs and Cosmetics Act.

III. issuance of guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 on the Website of CDSCO for purpose of uniform implementation of Drugs and Cosmetics Act in the Country.

IV. initiation of Whistle Blower Scheme to encourage vigilant Public Participation in the direction of Movement of spurious drugs in the country.

V. providing assistance for upgrading of testing facilities and establishing new drug testing laboratories under the Capacity Building project through Wold Bank, so as to enhance the capacity of the laboratories to test large number of samples.

VI. overseas inspection of drug manufacturing sites to ensure quality of imported bulk drugs.

VII. amendment of Schedule M to the Drugs and Cosmetics Rules, 1945, pertaining to Good Manufacturing Practices in 2001 to make it at par with the international standards. It is mandatory for the manufacturers of drugs to comply with requirements of this schedule for quality control of the drugs manufactured by them.

VIII. Introduction of Good laboratory Practices.

Annexure

Statement showing the Approvals & Expenditure of funds for the Head Procurement of Drugs under NHM during the F.Y. 2015-16
(Rs. In Crore)

Sl. No.	Activity	Child Health (JSSK) - Drugs & Consumables		Maternal Health (JSSK) - Drugs & Consumables		Procurement of Drugs and supplies	
		SPIP	Approvals	Exp.	SPIP	Approvals	Exp.
1	Bihar	3.07	0.36	34.44	3.47	130.71	7.33
2	Chattisgarh	1.63	0.10	10.18	1.73	49.74	0.01
3	Himachal Pradesh	0.50	0.80	3.88	3.38	26.47	10.92
4	Jammu & Kashmir	0.68	1.38	11.87	11.62	3.71	0.07
5	Jharkhand	1.62	0.31	20.33	5.50	29.17	2.13
6	Madhya Pradesh	1.00	0.09	31.54	11.49	91.73	34.32
7	Orissa	1.04	0.07	2.15	0.58	5.13	1.46
8	Rajasthan	3.20	0.22	46.19	3.67	130.20	8.71
9	Uttar Pradesh	0.00	0.13	127.00	15.59	153.00	18.35
10	Uttarakhand	0.94	0.01	4.40	0.79	19.48	1.35
11	Arunachal Pradesh	0.01	0.00	0.87	0.29	5.09	0.12
12	Assam	1.20	0.04	15.60	0.27	89.18	63.95
13	Manipur	0.07	0.08	1.62	0.78	1.57	0.29
14	Meghalaya	0.18	0.01	1.26	0.09	3.65	0.00
15	Mizoram	0.06	0.01	0.98	0.10	2.31	1.42
16	Nagaland	0.06	0.00	0.93	0.00	2.77	1.97
17	Sikkim	0.03	0.01	0.45	0.24	3.09	0.37
18	Tripura	0.14	0.06	2.55	0.43	9.91	0.66
19	Andhra Pradesh	0.54	0.00	16.48	1.96	29.26	0.00
20	Goa	0.07	0.01	0.45	0.01	2.20	0.10
21	Gujarat	1.92	0.93	24.84	4.70	50.84	3.12
22	Haryana	0.00	0.03	3.69	0.96	17.15	0.68
23	Karnataka	1.80	0.20	36.00	8.03	29.66	0.92
24	Kerala	0.45	0.08	8.97	2.04	4.93	0.00
25	Maharashtra	0.84	0.00	56.04	2.04	296.14	39.17
26	Punjab	0.85	0.01	13.72	0.69	61.31	32.87
27	Tamil Nadu	1.80	0.04	44.70	0.61	66.06	58.50
28	Telangana	0.00	0.00	14.70	0.85	20.80	0.00
29	West Bengal	2.28	7.63	54.52	21.34	24.74	12.96
30	A & N Islands	0.01	0.00	0.05	0.00	0.20	0.00
31	Chandigarh	0.00	0.00	1.63	0.00	0.00	0.00
32	Dadra & Nagar Haveli	0.02	0.00	0.24	0.00	0.65	0.00
33	Daman & Diu	0.01	0.00	0.06	0.00	0.15	0.05
34	Delhi	0.09	0.00	2.40	0.16	0.00	0.00
35	Lakshadweep	0.05	0.00	0.05	0.00	0.36	0.00
36	Puducherry	0.09	0.00	1.52	0.23	1.34	0.48
Total		26.24	12.59	596.29	103.65	1362.67	302.29

Note:
1) Figures of Expenditure are as per FMR, hence provisional.
2) Expenditure is inclusive of previous years unspent balance.
3) SPIP and Exp. stands for State Programme Implementation Plan and Expenditure.